Notice of Allowability

Application No.	Applicant(s)		
10/629,318	FEINBERG, ANDREW P.		
Examiner	Art Unit		
DIANA JOHANNSEN	1634		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTQL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFB 1.313 and MPEP 1308. This communication is responsive to the Amendment and Response filed 12/17/10; the interview of 3/7/11. The allowed claim(s) is/are 1,9,10,12,13,16,17 and 23-27. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) Thereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6.

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

1.	☐ Notice of

- References Cited (PTO-892)
- Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08).
- Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit
- of Biological Material

- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413). Paper No./Mail Date part of 20110308.
- 7. X Examiner's Amendment/Comment
- 8. T Examiner's Statement of Reasons for Allowance

9. 🔲 Other	
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/Diana B. Johannsen/ Primary Examiner, Art Unit 1634

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EXAMINER'S AMENDMENT

1. This action is responsive to the Amendment and Response filed December 17, 2010 and the interview of March 7, 2011. Claims 1, 9-10, 12-13, 16-17, and 23-27 are now allowed, subject to the examiner's amendment below. It is noted that claims 9-10, 12-13, 16-17, and 23-27 will be renumbered as claims 2-12 in the issued patent (see 37 CFR 1.126). Original claim numbering is employed in the examiner's amendment.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa A. Haile on March 7. 2011.

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3. The application has been amended as follows:

- a) Amend claim 9 as follows:
- 9. The method of claim 1, wherein the analysis is performed by contacting the biological sample with a primer pair comprising <u>at least one pair of:</u>

SEQ ID NO:2 and SEQ ID NO:3;

SEQ ID NO:4 and SEQ ID NO:5;

SEQ ID NO: 27 and SEQ ID NO: 28; and

SEQ ID NO: 29 and SEQ ID NO: 30.

- b) In claim 17, at line 2, after "comprising analyzing a" delete "first".
- In the specification, at page 1, the last line of paragraph 1, after "10/336,552, filed on January 3, 2003" insert--, now U.S. Patent No. 7,611,870--.

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Summary of the interview of March 7, 2011

4. On March 7, 2011, the examiner contacted applicant's representative to discuss allowance of the application. The examiner noted that the species election applicable to the primer pairs of claim 9 would be withdrawn in view of the allowability of generic claim 1, and indicated that claim 9 could now be amended to recite the previously withdrawn primer pairs. The examiner also suggested that claim 17 could be amended to delete the word "first" in line 2 as the claim only references one "genomic DNA sample" (and noted that alternatively she would include a clarifying comment indicating that the term "the genomic DNA sample" was interpreted as referencing the "first genomic DNA sample"). Applicant's representative authorized both of the proposed claim amendments, and also authorized the examiner to update the first line of the specification to recite the parent patent number.

Withdrawal of species election

5. Claim 1 is allowable. Claim 9, encompassing species previously withdrawn from consideration as a result of a restriction/election requirement, requires all the limitations of an allowable claim. Pursuant to the procedures set forth in MPEP § 821.04(a), the species election requirement set forth in the Office action mailed on October 29, 2008, is hereby withdrawn and the additional species of claim 9 have been rejoined and are allowed. In view of the withdrawal of the restriction/election requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or

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nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANA JOHANNSEN whose telephone number is (571)272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Diana B. Johannsen/ Primary Examiner, Art Unit 1634